In re of Appln. No. 09/936,922

REMARKS

Paper No. 13, the Office Action mailed December 3, 2002, has been carefully reviewed. The claims in the application are now claims 1-8 and 17-26, and these claims define patentable subject matter warranting their allowance. Applicant respectfully requests favorable consideration and early formal allowance.

Acknowledgement by the PTO of the receipt of applicant's papers filed under Section 119 is noted.

The election of species requirement has been repeated and made final, whereby claims 7, 15, 21-24 and 32 have been withdrawn from further consideration. Of these, claims 15 and 32 have been deleted, whereas claims 7 and 21-25 are retained.

Applicant respectfully repeats the traversal and reserves the right to petition this matter prior to allowance or an appeal as permitted according to the Rules.

Accordingly, applicant respectfully repeats by reference the commentary of the Reply of September 13, 2002. Applicant notes that according to PCT Rules 13.1 and 13.2, there is no lack of unity of invention because the same

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special technical feature exists throughout all the claims.

Consequently, the requirement, even if it were proper under

U.S. practice, is not proper under PCT practice which the PTO

is obligated to follow in the present application by

International Treaty.

Claims 8, 16, 18 and 26 have been objected to as using both full chemical names and abbreviations. The objection is respectfully traversed.

Applicant does not see how presenting both full chemical names and abbreviations would make the claims objectionable. Nevertheless, in deference to the examiner's views, claims 8 and 26 have been amended to delete the abbreviations. Claim 16 has been deleted. Claim 18 contains no abbreviations. Original claim 36 did include abbreviations, but it has been deleted.

The amendments to delete abbreviations are clearly not "narrowing" amendments. No limitations are added in this regard and none are intended.

Claims 3-6, 8, 18-20, 25 and 26 have been rejected under the first paragraph of \$112. This rejection is respectfully traversed.

Nevertheless, to advance prosecution, reference to

"prevention" has been deleted from the claims in which such language explicitly appeared, i.e. claims 3, 4, 17 and 18. This obviates the rejection. However, and for the record, applicant does not abandon "prevention", and respectfully reserves the right to pursue "prevention" claims in a continuing application without any prejudice whatsoever, applicants relying on rights granted under the law, including rights provided under \$\$119 and 120.

Claims 3-36 have been rejected under the second paragraph of \$112. This rejection is respectfully traversed.

As regards claims 9-16 and 27-36, which have been simultaneously also rejected under \$101, these non-statutory claims are now deleted as redundant and therefore unnecessary, and to conform to U.S. practice. No abandonment is intended of any subject matter.

Claims 3, 4, 7, 8, 17-19 and 21-26 have been rejected, but the rejection makes no criticism of these claims. Accordingly, if these claims are rejected, applicant does not know why, and cannot respond. Accordingly, applicant must assume that these claims were included inadvertently and erroneously, and that no rejection is intended of these claims.

The Office Action does criticize claims 5, 6 and 20.

As regards claim 20, there is no inconsistency between claims

18 and 20; clearly, schizophrenia is a disorder other than

dementia, and is fully supported by claim 18.

As regards claims 5, applicant has some considerable difficulty in understanding the position of the PTO. The rejection states that the "two subgenus are not mutually exclusive" leading to an assertion that the claims are "indefinite". The fact that in each claim the two mentioned terms are indeed mutually not exclusive, rendering some overlap between each set of terms, does not render any of the terms as "indefinite". Such an internal partial overlap does not interfere with definiteness. In particular, "dementia mental disorder" and "neuro-degenerative disorders" of claim 5 are well defined in the art. The same goes for "schizophrenia" and "dementia" of claim 6.

The terms used for mental conditions, their diagnoses and their causes have tended to change over the years. What may today be called dementia may next week be called a neuro-degenerative disorder or disease, or vice versa. The causes of these various diseases and thus their broad classification is presently in a state flux, as it has been for perhaps the last thirty or more years, and it is only

reasonable for applicant to select terminology which will be inclusive of the various conditions which are alleviated by the method according to the present invention.

Nevertheless, in deference to the examiner's views, rather than using classic Markush language, claim 5 is amended above to use other language which it is believed should not be criticized. No difference in coverage is intended, and no limitations have been added by the amendment of claim 5 above.

As amended, claim 5 should now be even more clear that the mental disorder or disease may be a dementia mental disorder or disease, or a neuro-degenerative disorder or disease, or a disorder or a disease which falls within both groupings of dementia and neuro-degenerative.

As regards claim 6, it has now been amended to depend from claim 4. As regards both claim 6 and claim 20, applicant disagrees with the assertion in the rejection that schizophrenia is a dementia. While it is true that the term "schizophrenia" was initially termed as "dementia praecox", this terminology was abandoned many years ago as confusing and misleading. It is well known today that schizophrenia may include, among other symptoms, hallucinations and multiple personality disorder. Dementia includes lose of memory and physiological loss of cognitive functions. They are

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different.

Attached is a copy of page 470 from "Dorland's Illustrated Medical Dictionary", 29th Ed. (2000) which defines "dementia". On the same page, find "d. prae'cox" and what follows is the terminology "(obs.)", meaning obsolete. Also attached is a print out from "On-line Medical Dictionary" from November 18, 1997 (copyright 1997-2003) for "schizophrenia".

There is no doubt that schizophrenia is **not** a dementia.

Applicant respectfully requests withdrawal of the rejection under the second paragraph of \$112.

Claims 1-8 and 17-26 have been rejected as obvious under \$103 from Chun et al USP 6,150,345 (Chun) in view of Piazza et al USP 5,565,439 (Piazza) or (as understood) alternatively various Kobayashi et al citations (apparently, as understood, any one of citations AG, AH, AI and AJ), hereinafter collectively "Kobayashi". This rejection is respectfully traversed.

Piazza and Kobayashi disclose the use of acylglycerol phosphates for treating hyperproliferative conditions (Piazza), as tumor metastasis inhibitor (ref. AG), as an antitumor agent (ref. AH) and as an antitumor agent

(ref. AI). In Piazza, it is indeed disclosed that lysophoshatidic acid (LPA) and derivative thereof such a acyl 1,2-glycerophosphates may be used for treating hyperproliferative conditions, hence the connection between LPA and acyl 1,2-glycerophosphates. Only reference AJ (Kobayashi et al, Database assesion number 123:350234) discloses the use of such glycerophosphates for treatment of dementia.

However, in the definition of the compound of claim 1, derivatives of acyl 1,2-glycerophosphates are excluded. The definition clearly reads "provided that when Y is $-(CH_2)_m$ -, m=0 and R is H or cation, X is not CH_2Oacyl ". When m=0, the compound of formula is a 1,2-glycerophosphate and indeed the "(CH_2)Oacyl" derivative was excluded. In view of the objection, applicant has added the same proviso to claim 17.

Accordingly, even if the combination were obvious as proposed, such combination would not reach the claimed subject matter. Applicant respectfully requests withdrawal of the rejection.

Applicant notes that PTO considers employing 1,3 cyclic glycerophosphate for treating schizophrenia as being allowable. Applicant accordingly understands that such subject matter is deemed by the PTO to define novel and

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unobvious subject matter under §\$102 and 103.

Favorable reconsideration and allowance are earnestly solicited.

Respectfully submitted,

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delusion that is patently absurd and has no possible such as delusions of being controlled or thought broad-

, the delusion that one's thoughts, feelings, and actions s own but are being imposed by someone else or by

1., a delusion that is congruent with a predominant deod, such as a delusion that one is being persecuted be-3's sinfulness or inadequacy, somatic delusions of serinihilistic delusions, or delusions of poverty.

ed d., a delusion that has no significant effect on behav-

d., a delusional conviction that some other person, usuer status and often famous, is in love with the individual; the subtypes of delusional disorder.

y d's, unconnected delusions not organized around a

leur, grandiose d., a delusion involving an exaggerated one's importance, power, or knowledge or that one is, pecial relationship with, a deity or a famous person; it is subtypes of delusional disorder.

usy, a delusional belief that one's spouse or lover is unsed on erroneous inferences drawn from innocent events to be evidence and often resulting in confrontation with ed. It is one of the subtypes of delusional disorder.

dentification, delusional misidentification.

one in which no central theme predominates; one of the

igruent d., a delusion occurring as a manifestation of a of delusional disorder. order; see also mood-congruent.

ongruent d., a delusion occurring as a manifestation of a

: disorder; see also mood-incongruent. ation, nihilistic d., a depressive delusion that the self or ie self, part of the body, other persons, or the whole world

I d's, an older term denoting delusion of grandeur and de-

persecution; its use is discouraged. recution, persecutory d., a delusion that one is being atharassed, cheated, persecuted, or conspired against; it is ne subtypes of delusional disorder.

verty, a delusion that one is, or soon will be, bereft of ma-

ference, a delusional conviction that ordinary events, obbehaviors of others have an unusual or peculiar meaning ally for oneself. When less frequent or intense, or if not oror systematized, such beliefs are called ideas of reference. : d., a delusion that there is some alteration in a bodily organ inction; it is one of the subtypes of delusional disorder. atized d's, a group of delusions organized around a common

on-al (də-loo'zhən-əl) pertaining to or characterized by de-

al (del'vĭ-nəl) trademark for preparations of vinbarbital.

dex (de'ma-deks) trademark for preparations of torsemide.

•sia (de-man'se-a) a genus of venomous snakes of the fampidae, including the brown snake of Australia and New Guinea.

*ca-tion (de"mahr-ka'shən) [L. demarcare to limit] the ng off or ascertainment of boundaries.

ze d., any dividing line apparent on the surface of a solid body, as the boundary between living and necrotic tissue.

r-quay's sign (d>-mahr-kāz') [Jean Nicholas Demarquay, :h surgeon, 1814–1875] see under sign.

s·cu·lin·iza·tion (de-mas"ku-lin"i-za'shən) the loss of nornale secondary sex characters; when hormonal in nature it may ecompanied by testicular atrophy and involution of the pros-See also feminization.

at-i-a-ceae (de-mat"i-a'se-e) in some systems of classificaa form-family of Fungi Imperfecti of the form-order Moniliales, lucing simple conidiophores, and having dark brown or black dia, spores, or hyphae. Genera of medical importance include moniella, Alternaria, Arthrographis, Aureobasidium, Bipolaris, losporium, Curvularia, Dematium, Drechslera, Exophiala, Exserom, Fonsecaea, Madurella, and Phialophora. 1 dark brown to black in

deme (dēm) [Gk. dēmos common people] a population of ver ilar organisms interbreeding in nature and occupying a city scribed area; called also genetic population.

we-ca-ri-um (dem"-kar'e-m) an anticholinesterase used topically to produce miosis, reduce intraocular pressure potentiate accommodation in the treatment of open-angle glain potentiate accommodative convergent strain dem·e·ca·ri·um (dem"ə-kar'e-əm) and in the management of accommodative convergent strain d. bromide [USP], a potent, long-acting cholinesterase inhibition plied topically to the conjunctiva in the treatment of glaucone convergent strabismus.

dem·e·clo·cy·cline (dem"ə-klo-si'klēn) [USP] [MeSH: Dem cline] a broad-spectrum oral antibiotic of the tetracycline produced by a mutant strain of Streptomyces aureofaciens of synthetically. It also inhibits the effect of antidiuretic horm the renal tubules. Called also demethylchlortetracycline. d. hydrochloride [USP], the monohydrochloride salt of den cycline, administered orally. It is also used as a diuretic.

de-ment-ed (da-men'tad) deprived of reason, mentally rated; affected with dementia.

de-men-tia (də-men'shə) [de- + L. mens mind] [MeSH: Den [DSM-IV] a general loss of cognitive abilities, including impair of memory as well as one or more of the following: aphasia, of memory as well as one or more of the following: aphasia, and agnosia, or disturbed planning, organizing, and abstract the second control of the following: aphasia, and approximately abilities. It does not include loss of intellectual functioning by clouding of consciousness (as in delirium), depression, of functional mental disorder (pseudodementia). Causes indilarge number of conditions, some reversible and some programme that result in widespread cerebral damage or dysfunction. The common cause is Alzheimer's disease; others include ceres cular disease, central nervous system infection, brain trauma mors, vitamin deficiencies, anoxia, metabolic conditions, end conditions, immune disorders, prion diseases, Wernicke-Kon syndrome, normal-pressure hydrocephalus, Huntington's multiple sclerosis, and Parkinson's disease.

alcoholic d., Korsakofi's syndrome.

Alzheimer's d., see under disease. d. of the Alzheimer type [DSM-IV], that occurring in Alzheimer disease, being of insidious onset and gradually progressive with histopathological changes characteristic of Alzheimer ease and not due to other central nervous system, systemical stance-induced conditions known to cause dementia. It is terized as early onset or late onset depending on whether it by the age of 65, and is subcategorized on the basis of ago nying features, including delirium, delusions, depressed more havioral disturbances, or none (uncomplicated).

arteriosclerotic d., multi-infarct dementia as a result of cer

teriosclerosis.

Binswanger's d., see under disease.

boxer's d., a syndrome more serious than boxer's traum cephalopathy, the result of cumulative cerebral injuries in thinking, dize characterized by forgetfulness, slowness in thinking, disense in the thinking in the think speech, and slow, uncertain movements, especially of the speech, and slow, different industrial encephalopathy, and called also d. pugilistica, punch-drunk encephalopathy, and called

dialysis d., see under encephalopathy. epileptic d., a progressive mental and intellectual deterioral occurs in a small fraction of cases of epilepsy; it is thought to be caused by neuronal degeneration secondary to circulate to the caused by neuronal degeneration secondary to circulate the caused by neuronal degenera disturbances during seizures.

myoclonic d., d. myoclo'nica, mental deterioration w oclonus, as seen in disorders such as Alpers' disease, Cre Jakob disease, subacute sclerosing panencephalitis, and

mer's disease. paralytic d., d. paraly'tica, general paresis.

posttraumatic d., dementia following head injury or other trauma; it may last from a few months to years. Cf. boxe postconcussional syndrome.

d. prae'cox, (obs.) schizophrenia.

presenile d., that occurring in younger persons, usually in age 65 or younger; since most cases are due to Alzheimer's the term is sometimes used as a synonym of d. of the Alzheil early onset, and has also been used to denote Alzheimer's primary degenerative d., severe loss of intellectual function discernible cause; it generally denotes dementia of the Attype but may be used for that associated with Pick's disease d. pugilis'tica, boxer's d.

senile d., that occurring in older persons, usually over n older persons, usually over the

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schizophrenia

<psychiatry> A mental disorder or heterogeneous group of disorders (the schizophrenias or schizophrenic disorders) comprising most major psychotic disorders and characterised by disturbances in form and content of thought (loosening of associations, delusions and hallucinations) mood (blunted, flattened or inappropriate affect), sense of self and relationship to the external world (loss of ego boundaries, dereistic thinking and autistic withdrawal) and behaviour (bizarre, apparently purposeless and stereotyped activity or inactivity).

The <u>definition</u> and <u>clinical application</u> of the <u>concept</u> of the concept of schizophrenia have varied greatly. The DSM III R criteria emphasise marked <u>disorder</u> of thought (<u>delusions</u>, <u>hallucinations</u> or other thought disorder accompanied by disordered <u>affect</u> or <u>behaviour</u>), <u>deterioration</u> from a previous level of functioning and <u>chronicity</u> (<u>duration</u> of more than 6 months), <u>thus</u> excluding from this <u>classification</u> <u>conditions</u> referred to by others as <u>acute</u>, borderline, <u>simple</u> or <u>latent</u> schizophrenia. Originally called <u>dementia</u> praecox and characterised as a <u>psychosis</u> with <u>adolescent</u> onset and a <u>chronic course ending</u> in deterioration. The <u>term</u> schizophrenia was <u>introduced</u> by Bleuler because neither <u>early</u> onset nor <u>terminal</u> deterioration is an <u>essential</u> feature, he emphasised the <u>splitting</u> and <u>lack</u> of <u>personality integration</u> seen in the disorder.

Origin: Gr. Phren = mind

(18 Nov 1997)

Previous: <u>schizonemertea</u>, <u>schizont</u>, <u>schizonticide</u>, <u>schizonychia</u>, <u>schizopelmous</u>, <u>schizophasia</u> **Next**: schizophrenia and disorders with <u>psychotic features</u>

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